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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,629	04/16/2004	Don Jeffrey Diamond	1954-394	8000

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EXAMINER

SALIMI, ALI REZA

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/825,629	<b>Applicant(s)</b> DIAMOND ET AL.	
	<b>Examiner</b> A R. Salimi	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/9/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-14 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6 are vague and indefinite for recitation of “antigenic fragment thereof”, the intended fragment is not defined. The claims have been interpreted in light of the specification and the disclosure shows only intact Ub-to-cytomegalovirus gene construct, no fusion of partial gene to UB is disclosed. Thus, the intended metes and bounds of the fragments is/are not defined. This affects the dependent claims.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6, are rejected under 35 U.S.C. 102(a) as being anticipated by Paoletti et al (US patent No. 6,632,438 B2).

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The product of the claimed invention is clearly anticipated by the above cited patent.

Paoletti et al taught expression of cytomegalovirus proteins utilizing poxvirus vectors in general and NYVAC and ALVAC in particular, including pp65, pp150, IE1, and gB (see claims 1-9).

Claims 1-4, 6-14 are rejected under 35 U.S.C. 102(a) as being anticipated by La Rosa et al (Immunobiology, Blood, November 2002, Vol. 100, No. 10, pages 3681-3689).

The above-cited reference taught fusion of cytomegalovirus genes to human ubiquitin gene and determined that the construct induced enhanced immune response in mice (see page 3682, right column, 1-3<sup>rd</sup> full paragraph, and page 3687, right column 2<sup>nd</sup> full paragraph).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, are rejected under 35 U.S.C. 102(e) as being anticipated by Paoletti et al (US patent No. 6,632,438 B2).

The product of the claimed invention is clearly anticipated by the above cited patent.

Paoletti et al taught expression of cytomegalovirus proteins utilizing poxvirus vectors in general and NYVAC and ALVAC in particular, including pp65, pp150, IE1, and gB (see claims 1-9).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al (US patent No. 6,632,438 B2), and Sutter et al (US Patent No. 6,440,422 B1).

As stated above Paoletti et al taught expression of cytomegalovirus proteins utilizing poxvirus vectors in general and NYVAC and ALVAC in particular, including pp65, pp150, IE1, and gB (see claims 1-9). This differs since they did not disclose a well known Modified vaccinia Ankara virus.

Sutter et al taught Modified Vaccinia Ankara Virus as a general expression vector for expression of foreign antigen.

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated to use the expression vector taught by Sutter et al and insert the construct taught by Paoletti et al to induce immune response, absent any unexpected results. Paoletti et al had already disclosed that cytomegalovirus genes could be expressed in an attenuated vaccinia vector, and Sutter et al disclosed another attenuated vaccinia suitable for expression of foreign antigens. Thus, substituting Paoletti's et al expression vector with Sutter et al would have been obvious. Hence, the invention as a whole is prima facie obvious absent any unexpected results.

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Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over La Rosa et al (Immunobiology, Blood, November 2002, Vol. 100, No. 10, pages 3681-3689), and Sutter et al (US Patent No. 6,440,422 B1).

As stated above La Rosa et al taught fusion of cytomegalovirus genes to human ubiquitin gene and determined that the construct induced enhanced immune response in mice (see page 3682, right column, 1-3<sup>rd</sup> full paragraph, and page 3687, right column 2<sup>nd</sup> full paragraph). This only differs since they did not use Modified vaccinia Ankara virus.

Sutter et al taught Modified Vaccinia Ankara Virus as a general expression vector for expression of foreign antigen.

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated to use the expression vector taught by Sutter et al and insert the construct taught by La Rosa et al to induce immune response, absent any unexpected results. La Rosa et al had disclosed that fusion of UB genes with cytomegalovirus genes could be expressed in an attenuated vaccinia vector, and Sutter et al disclosed another attenuated vaccinia suitable for expression of foreign antigens. Thus, substituting La Rosa's et al expression vector with Sutter et al would have been obvious. Hence, the invention as a whole is prima facie obvious absent any unexpected results.

No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

1/20/2006

  
ALI R. SALIMI  
PRIMARY EXAMINER